



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

UMAÑA *et al.*

Appl. No.: 10/633,697

Filed: August 5, 2003

For: **Glycosylation Engineering of  
Antibodies for Improving  
Antibody-Dependent Cellular  
Cytotoxicity**

Confirmation No.: 5455

Art Unit: 1636

Examiner: David Guzo

Atty. Docket: 1975.0010005/TJS/T-M

**First Supplemental Information Disclosure Statement  
Filing under 37 C.F.R. § 1.97(c)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on October 28, 2004, in connection with the above-captioned application. Copies of the cited documents are submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO/SB/08B based on information presently available to the undersigned. However, the listed

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publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

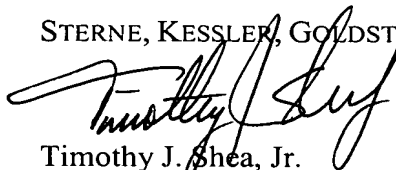
This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our card payment form PTO-2038 in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO/SB/08B, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

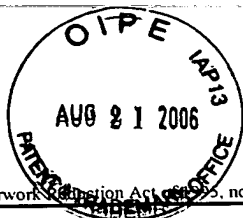


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<b>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/633,697		
		Filing Date	August 5, 2003		
		First Named Inventor	Pablo UMAÑA		
		Art Unit	1636		
		Examiner Name	David Guzo		
Sheet	1	of	2	Attorney Docket Number	1975.0010005/TJS/T-M

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AT50	Edge, C.J., <i>et al.</i> , "The conformational effects of N-linked glycosylation," <i>Biochem. Soc. Trans.</i> 21:452-455, Portland Press (1993)	
	AR51	Jefferis, R. and Lund, J., "Glycosylation of Antibody Molecules: Structural and Functional Significance," <i>Chem. Immunol.</i> 65:111-128, Karger (January 1997)	
	AS51	Jefferis, R., <i>et al.</i> , "Effector mechanisms activated by human IgG subclass antibodies: clinical and molecular aspects," <i>Ann. Biol. Clin.</i> 52:57-65, John Libbey Eurotext (1994)	
	AT51	Jefferis, R., <i>et al.</i> , "IgG-Fc-mediated effector functions: molecular definition of interaction sites for effector ligands and the role of glycosylation," <i>Immunol. Rev.</i> 163:59-76, Munksgaard (June 1998)	
	AR52	Nakamura, K., <i>et al.</i> , "Chimeric Anti-Ganglioside G <sub>M2</sub> Antibody with Antitumor Activity," <i>Cancer Research</i> 54:1511-1516, American Association for Cancer Research (1994)	
	AS52	Rothman, R.J., <i>et al.</i> , "Antibody-Dependent Cytotoxicity Mediated by Natural Killer Cells Is Enhanced by Castanospermine-Induced Alterations of IgG Glycosylation," <i>Mol. Immunol.</i> 26:1113-1123, Pergamon Press (1989)	
	AT52	Rothman, R.J., <i>et al.</i> , "Clonal Analysis of the Glycosylation of Immunoglobulin G Secreted by Murine Hybridomas," <i>Biochemistry</i> 28: 1377-1384, American Chemical Society (1989)	
	AR53	Routier, F.H., <i>et al.</i> , "The glycosylation pattern of a humanized IgG1 antibody (D1.3) expressed in CHO cells," <i>Glycoconjugate J.</i> 14:201-207, Chapman & Hall (February 1997)	
	AS53	Shitara, K., <i>et al.</i> , "A new vector for the high level expression of chimeric antibodies in myeloma cells," <i>J. Immunol. Methods</i> 167:271-278, Elsevier Science (1991)	
	AT53	Standley, S. and Baudry, M., "The role of glycosylation in ionotropic glutamate receptor ligand binding, function, and trafficking," <i>Cell. Mol. Life Sci.</i> 57:1508-1516, Birkhäuser Verlag (October 2000)	

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Application Number	10/633,697	
				Filing Date	August 5, 2003	
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				Art Unit	1636	
				Examiner Name	David Guzo	
Sheet	2	of	2	Attorney Docket Number		1975.0010005/TJS/T-M
	AR54	Standley, P., <i>et al.</i> , "CHO cells provide access to novel N-glycans and developmentally regulated glycosyltransferases," <i>Glycobiol.</i> 6:695-699, Oxford University Press (1996)				
	AS54	Youakim, A. and Shur, B.D., "Alteration of Oligosaccharide Biosynthesis by Genetic Manipulation of Glycosyltransferases," <i>Ann. N.Y. Acad. Sci.</i> 745:331-335, New York Academy of Sciences (1994)				
	AT54	Wright, A., and Morrison, S.L., "Effect of Altered C <sub>H</sub> 2-associated Carbohydrate Structure on the Functional Properties and In Vivo Fate of Chimeric Mouse-Human Immunoglobulin G1," <i>J. Exp. Med.</i> 180:1087-1096, The Rockefeller University Press (September 1994)				

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